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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/851,372	05/07/2001	Michael R. Forman	20534-000500	2385

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EXAMINER	
WILLIAMS, CATHERINE SERKE	
ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 11/18/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/851,372	FORMAN, MICHAEL R.	
	Examiner	Art Unit	
	Catherine S. Williams	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *3,4 and 18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-17 and 19-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The terminal disclaimer filed 9/8/03 has been entered into the file.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (f) he did not himself invent the subject matter sought to be patented.

Claims 1,8-17 and 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Hastings et al (US Pat# 5,951,458).

Hastings discloses a local application of oxidizing agents and radiation to prevent restenosis. The device includes a catheter body having a proximal end and a distal end (see figure 15). An ionizing radiation source (see 13:50-65) is coupleable to the catheter body within a balloon for applying a radiation dose to a body lumen. Means including infusion holes (372), hydrogel (matrix) coated balloons, or a microporous balloon are coupleable to the catheter body for releasing a therapeutic agent. The therapeutic agent is capable of being a radiosensitizer. The radiation and drug delivery catheter is used to inhibit hyperplasia (see summary). It is considered inherent that the hydrogel coating is a rate controlling material that releases the agent

through diffusion, degradation of the matrix and from pores in the material. The device also includes a helical balloon (perfusion threading) to allow for blood flow through the treatment area.

Claims 1-2 are rejected under 35 U.S.C. 102(e) as being anticipated by Forman et al (US Pat# 6,390,967).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Forman discloses a radiation catheter for inhibiting hyperplasia after intravascular intervention that includes a catheter body having a proximal end and a distal end (see figure 6A). An ionizing radiation source (22" ; x-ray) is coupleable to the catheter body for applying a radiation dose to the body lumen. Means for releasing (46) are coupleable to the catheter body. The means are capable of releasing a radiosensitizer to the body lumen.

Claims 1-2 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. The prior art (Forman et al '967) discloses the invention as claimed and includes inventors in addition to the inventor of the instant application. Hence, the device in claims 1 and 2 was derived from the invention of the inventive entity (the three inventors) of the prior art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hastings ('458) in view of Tachibana et al (US Pat# 6,176,842).

Hastings meets the claim limitations as described above but both fail to discloses a source of at least one radiosensitizer selected from the group listed in claim 5 and the radiosensitizer being attached or encapsulated in a lipid or surfactant carrier.

However, Tachibana discloses an ultrasound assembly for use with light activated drugs that includes the administration of taxol within a lipid carrier. The administration is for the destruction of rapidly growing tissue.

At the time of the invention, it would have been obvious to incorporate the administration of taxol within a lipid carrier into the invention of Hastings. The devices are analogous in the art and used to treat tissue that is proliferating. The motivation for the incorporation would have been in order to enhance the application of the invention of Hastings.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hastings ('458) in view of Tachibana et al (US Pat# 6,176,842).

Hastings in view of Tachibana meet the claim limitations as described above but fail to include incorporating taxol into a solution with polyoxyethylated castor oil and dehydrated alcohol.

At the time of the invention, it would have been obvious to incorporate taxol into a solution with polyoxyethylated castor oil and dehydrated alcohol. Tachibana teaches the use of liposomes and a solution with polyoxyethylated castor oil and dehydrated alcohol is an equivalent in the art. The motivation for the substitution would have been an obvious design choice. The disclosure of the instant application has asserted no advantage, particular purpose or solution to a problem for the inclusion of incorporating taxol into a solution with polyoxyethylated castor oil and dehydrated alcohol. Therefore the motivation for the substitution would have been to utilize readily available materials for ease of production.

Response to Arguments

Applicant's arguments filed 9/8/03 have been fully considered but they are not persuasive. Applicant traverses the rejection of claims 1,8-17 and 19-21 under 35 U.S.C. § 102(b) by Hastings because the reference fails to teach "a source of at least one radiosensitizer", means for releasing a radiosensitizer, and a combined radiation and radiosensitizer delivery catheter to inhibit hyperplasia.

Claim 1 does not recite "a source of at least one radiosensitizer" and for that matter does not positively recite the limitation of even a radiosensitizer. Therefore, the prior art (Hastings) does not have to teach this limitation in order to be applied as a 102(b) reference for this claim. The examiner reminds applicant that functional language may not define a claim over the prior art if the prior art is capable of performing that function. If a prior art structure is capable of

performing the intended use then it meets the claim. See, e.g., In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997) (anticipation rejection affirmed based on Board's factual finding that the reference dispenser (a spout disclosed as useful for purposes such as dispensing oil from an oil can) would be capable of dispensing popcorn in the manner set forth in appellant's claim 1 (a dispensing top for dispensing popcorn in a specified manner)). Additionally, applicant refers to part of the Office Action (page 5) that does not pertain to the 35 U.S.C. § 102(b) by Hastings but rather a 103 rejection using Hastings as the primary reference. Therefore, this argument is moot and irrelevant.

Applicant's own specification defines "means for releasing a radiosensitizer", among other structures, as "at least one microporous balloon on the catheter body". See page 5 line 30-31 of the instant specification. Hastings discloses the use of a microporous ballon for delivery of an oxidizing agent through the pores to the vessel wall. See 17:28-32. Therefore, Hastings discloses the exact structure as defined in applicant's own specification. The prior art meeting this limitation could not be more clear.

Finally, Applicant argues that the delivery and radiation therapy in Hastings are performed independently and therefore does not read on the "combined" aspect of the instant invention. This is not claimed. Whether performed at the same time or one before or after the other both treatments are used to inhibit restinosis. The term "combined" does not inherently mean at the same time or simultaneously.

Regarding applicant's argument to the use of the Forman reference (US Pat# 6,390,967) in the 102(e) and 102(f) rejections, the radiosensitizer is not positively recited in the claims. Claim 1 only includes the radiosensitizer in functional language. A recitation with respect to the manner in which a claimed apparatus is intended to be used does not differentiate the claim from

a prior art device if the prior art teaches all the structural limitations of the claim. Therefore, a radiosensitzer is not required in the Foreman reference. The only requirement is that Foreman shows "means for releasing" that is a structural equivalent of those disclosed in the instant specification and that the prior art "means" are capable of being used with a radiosensitizer. The instant specification discloses that infusion ports 46 are for releasing a radiosensitizer. See page 12 lines 25-26. These same infusion ports are disclosed in the prior art.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 703-308-4846. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone numbers for the

organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-2192.

Catherine Serke Williams
November 4, 2003

BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700